

We are announcing an upcoming Round Table event: **“Pulsed Field Ablation for Atrial Fibrillation: Safety, Efficiency, and Regulatory Knowledge Gaps”** that will take place during the Electroporation-Based Technologies and Treatments International Scientific Workshop and Postgraduate Course (EBTT). This hybrid (both online and on-site) event will bring together key stakeholders, including representatives from the U.S. Food and Drug Administration, academia, and medical device industry.

Webinar: live online and on-site

15:00-17:30 (CET), November 16, 2023 | University of Ljubljana – Ljubljana, Slovenia

Round Table event: “Pulsed Field Ablation for Atrial Fibrillation: Safety, Efficiency, and Regulatory Knowledge Gaps”

Attendees of this round table will discuss regulatory knowledge gaps affecting establishing Pulsed Field Ablation (PFA) devices safety and effectiveness, explore novel science-based approaches and methodologies for PFA devices testing and evaluation, including alternatives to animal testing that have the potential to accelerate patient access to safe and effective treatment of atrial fibrillation. The insights generated from this round table discussion will inform the direction of future efforts to address major challenges and gaps affecting PFA device development and regulatory review.

Please note: Attendance is free and open to anyone interested, however, registration for both online and on-site participation is mandatory. On-site presence is limited due to limited space available.

The topics and speakers – the program of the FDA-industry-academia round table:

1. What are the safety concerns related to PFA/cardiac ablation by electroporation (David Hazlewood – FDA/CDRH/OHT2, USA)
2. Regulatory science tools to accelerate PFA device development and regulatory decision making (Ksenia Blinova – FDA/CDRH/OSEL, USA)
3. Why and how cells are dying? (Rafael Davalos, Georgia Tech – Emory Biomedical Engineering, USA)
4. In vitro testing – can it be used and to what extent? (Maura Casciola – FDA/CDRH/OSEL, USA)
5. Temperature, electrochemistry – microbubble formation – Is there a risk? (Samo Mahnič-Kalamiza – University of Ljubljana, Slovenia)
6. Acute physiological effects of high voltage electric pulses – nerve stimulation, nerve paresis, vascular spasm, and coughing. (Antoni Ivorra – Universitat Pompeu Fabra, Barcelona, Spain)
7. Clinician’s (EP) perspective (Atul Verma – McGill University, Dept of Medicine, Div. of Cardiology, Montreal, Canada)
8. Understanding Pulsed Field Ablation (Daniel Sigg – Medtronic, USA)
9. Developing Pulsed Field Ablation Products for Cardiac Ablation: Lessons and Future Challenges (Scott Meyer – Boston Scientific, USA)
10. Numerical modeling for reducing time to market for next generation devices (Bor Kos – University of Ljubljana, Slovenia)
11. PFA: Important clinical questions to address (Vivek Reddy – Icahn School of Medicine at Mount Sinai, USA)
12. Pulse waveforms in PFA: to disclose or not to disclose (Damijan Miklavčič – University of Ljubljana, Slovenia)

Each of these topics above being introduced by the speaker who confirmed their participation, followed by discussion.